THE INSTRUMENTATION FOR PLACING INTRAOSSEOUS METALLIC IMPLANTS AND THEIR RELIABILITY

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

INTRODUCTION AND PURPOSE

Ever since the time that man first used the cephalometer in conjunction with the X-ray tube to study growth and dental changes in the skull, he has sought so-called stable points about which all other alterations occurred. Such points would enable him to assess the amount and direction of one change in relation to another.

The search continued from about 1930 until 1955 for one or a series of natural boney landmarks which satisfied the "stability" requirement and also were readily observable on the usual projections used--the lateral and posterior-anterior headplates.

In 1955, Dr. Arne Bjork described the use of metallic pins embedded in the mandibles and maxillas of Danish children. The pins served as artificial stationary landmarks to evaluate the growth of these two bones of the skull.[1] The stability of these markers was based on the body's non-reactivity to the material used, and to the fact that bone only grows by surface apposition and resorption. In other words, as long as the pins were embedded in the bone, they always remained at the same relation to each other as when placed. They could therefore be used as reference points from which measurements could be made, and as points which could be superimposed from one film to

another perhaps taken years apart.

Bjork points out that with growth, the mandibular implants even continue to stay the same distance from the film if a constant midsagittal plane-film distance is maintained. The implants merely wind up deeper in the bone due to surface apposition. The maxillary markers do get closer to the film with growth in width of the face because of the palatine suture. He feels that this change in enlargement is so slight, however, that its effect on the reliability of the points is negligible. Strangely, the only numerical reference made to the reliability or the accuracy of these reference points is a rather nonspecific statement made by Bjork in a 1963 article: "The accuracy with which the annual growth was recorded, determined on the basis of repeated measurements, lies within the limits of plus or minus 0.5 mm."[4]

The apparent need for a more complete documentation of the reliability of intra-boney metallic implants, coupled with the very rare use of such a technic on human subjects in this country stimulated the author to attempt a study of his own.

The purpose of this investigation was to develop a practical instrument and procedure for placement of intra-osseous metallic implants and to statistically analyze their reliability in a limited sample of human subjects.

The term reliability in this sense means the ability to reproduce or repeat a given observation or measurement.

It does not necessarily follow that because the observation or measurement can be repeated that it is also accurate or, stated conversely, free from error. The validity of the measurement and the investigator enter into the discussion here. In other words, is he actually repeating the measurement he says that he is, or is it a different but similar measurement between different points than those stated? If the measurement is valid and the investigator honest, reliability is a direct indication of the accuracy. This still does not mean that if the reliability is high, that the measurement is free from error. It can mean that error exists but is constant in all the measurements to the same degree.

The factors contributing to the unreliability of implants as measurement landmarks are many. The measurement error of the investigator and his equipment is a major factor. This includes his ability to locate the landmark from which the measurement will be made. The error involved in repositioning the patient in the head holder for subsequent films is probably the next factor in importance. Movement of the implants in the bone due to faulty placement and variations in the exposure and processing of the films constitute two of the many additional factors which all contribute to the total error involved in measuring between two points on a cephalometric lateral headplate.[9,18]

REVIEW OF THE LITERATURE

Although Bjork associates Ollier, a French investigator of the 1870's, with implants,[4] the Danish researcher is generally given credit for being first with their use as radiographic reference points in human subjects. Since that time in 1955, only three published studies have been done using metallic implants in concert with cephalometric radiography. Dr. Bjork's work will be reviewed first.

Bjork's work from 1955 to 1963 has amassed a sample of 110 children containing implants. He utilized a 90% tantalum, 10% tungsten material for the pins. The mandibular markers were located as follows: one at the symphysis, two at mid-body, and one on the lateral surface of the ramus. The maxilla contained pins at three or four locations high in the buccal vestibule. All placements were made on the right side. An intra-oral approach was used without utilizing any incisions. The implanting device was forced through the tissue overlying the bone, and the implant was malleted to place.

Dr. Bjork first utilized the markers to describe the changes observed in growth of a limited sample of patients, and this was presented in the form of five case presentations in 1955.[1] In 1963, a more complete work covering the entire sample of 110 was published.[4] This study dealt with the detailed growth changes occurring in the mandible over an 11 year period. The only mention of measurement error was that referred to in the introduction and purpose section.

In 1959, Krebs,[11] a student of Bjork's used Vitalium implants in a sample of nine patients requiring rapid palatal expansion. The markers were placed on the lingual alveolar process of the maxilla adjacent to the cuspid and along the infrazygomatic process of the maxilla on both sides. He utilized the same placement procedure as Bjork did. The movements of the basal and alveolar structures were followed as rapid expansion was done. No mention was made of measurement error.

In 1964, Isaacson and Murphy[10] reported on the use of implants to follow the alveolar and basal changes occurring in patients undergoing rapid palatal expansion who also had repaired complete clefts of the palate. The implants were fashioned from silver endodontic cones and were placed by means of a modified 18 gauge hypodermic needle after raising a small mucoperiosteal flap. The boney surface was also prepared for the reception of the implant by using a small inverted cone bur. The markers were placed in the zygomatic process, on the buccal alveolus of the maxilla between the buccal roots of the first molar, and on the lingual alveolus of the maxilla mesial to the apex of the lingual root of the first molar. Pins were located on both sides. The sample contained five subjects and no mention was made of reliability or measurement error.

Coccaro and Lloyd,[6] in 1965, reported using tantalum implants placed in the areas of point A and point B. Their sample contained two adult subjects who required dentures.

The implants were placed with the aid of an 18 gauge needle and malleted to place. A full flap was first raised, the anterior teeth were extracted, and the implants were malleted to place. Immediate dentures were inserted after the surgery. The study extended over a five year period, and the changes seen in points A and B were recorded. No mention is made concerning reliability or measurement error.

MATERIALS AND METHODS

This section is actually a summary of the apparatus and procedure used in the study. A complete detailed description is given in the appendix under the appropriate titles.

Tantalum-tungsten wire .022 inch in diameter was fashioned into pointed pins 1-1½ mm. in length and placed in the mandible and maxilla of each of seven subjects.

The sample group consisted of five adult males, one adult female, and one female orthodontic patient, age 7. This rather unhomogeneous group was selected not by design, but by availability and consent of the individuals. It was simply the only sample which could be used in the time allotted for the study.

The instrument used in placement, and the method of placing the implants were modifications of that used by Bjork.[1,4] Four of the subjects had at least three implants placed in each jaw. Two of the remaining individuals had two markers placed in the maxilla and three in the mandible. One subject received two pins in each jaw. This variability in number of placed implants per individual is explained in the appendix.

The implants were all placed using an intraoral approach. The mandibular sites were near the symphysis, mid-body

beneath the first molar, and near the anterior border of the ramus. The maxillary locations were in the palate lingually to the cuspid, on the anterior surface of the zygomatic process, and on the inferior surface of the zygomatic process. All implants were placed on the right side. The maxillary pins will be referred to as the anterior, middle, and posterior implants; which correspond with the palatal, zygomatic anterior surface, and zygomatic inferior surface locations, respectively, The mandibular markers will be referred to as the anterior, middle, and posterior implants; which correspond with the symphysis, mid-body, and ramus sites, respectively.

These areas were selected because it was felt that they were the best in terms of access, thickness of cortical plate necessary to support an implant, distance from the roots of the teeth, the presence of large blood vessels and nerves, and the degree of future surface resorption expected. Access should be such that the long axis of the implanter can be placed at right angles to the boney surface. The cortical plate over the nasal or sinus cavities should be considerably thicker than the 1 to 1½ mm. length of the implant. This is the reason for not using a posterior palatal site near the mid-line. The roots of adjacent teeth should be far enough distant that their movement during orthodontic treatment will not cause them to come into contact with the markers. Larger blood vessels and nerves such as the greater, palatine, incisive, and mental complexes should be avoided to prevent post-operative difficulties. Areas that remodel

with growth by undergoing considerable surface resorption should be avoided. This would eventually leave the implant in the moveable soft tissue, making it useless as a reliable measurement landmark. The areas superior to the mentalis and the sharp crest of the anterior border of the ramus are apparently the locations most affected by surface resorption.[4] (See appendix for details in selection of sites for implant placement.)

The placement procedure consisted of locating the desired areas by inspection and palpation, application of topical anesthetic, injection of local anesthetic at the site, a "stab" incision with #15 Bard-Parker blade, insertion of the tip of the loaded implanting device into the incision, and driving the implant to place in the bone by means of a mallet manned by an assistant.

The radiographic procedure consisted of exposing each subject three times at various intervals over approximately a two week period following placement of the implants. Standard cephalometric methods were followed with only slight modifications (see appendix). A self-centering headholder which maintained a constant midsagittal plane-film distance was used. Films were taken immediately after placement on three of the subjects and within one or two days on the remainder of the sample. Another was taken one week later, and another approximately two weeks after implant placement.

The films were utilized in the following manner: The

radiopaque areas representing the implants were punched in the geometric center with a sharpened modified straight explorer. Measurements were made between the punched holes with a Starrett rule graduated in ½ mm. This graduation allowed measurement to the nearest 1/10 mm.

The distances between implants within each jaw and the linear values from implants in the mandible to those in the maxilla were recorded. The differences between the measurements from the first film taken (A) and the second film recorded (B), the second film (B) and the third film (C), and the first film (A) and the third film (C) were calculated. This produced three sets of differences for implant measurements-- A-B, B-C, A-C.

Tracings were then made on all films for the cephalometric landmarks sella, nasion, orbitale, porion, incisal edge of upper right central incisor, and articulare. These same points were then punched on the films and the measurements repeated.

In addition to the above cephalometric landmarks, gnathion was punched on the films. Measurements were made between selected implants and four boney landmarks in the following fashion: anterior maxillary to nasion, anterior maxillary to sella, anterior maxillary to articulare, posterior mandibular to gnathion, posterior mandibular to articulare. Differences from films A, B, and C were calculated and recorded similarly to those for measurements between implants.

Figure 1. displays the reference points used in the study.

The statistic employed to evaluate reliability was the standard error of the measure (S.E.m.).[2,3,7,9] This statistic is actually a special form of pooled variance.[19] The formula for this statistic is S.E.m.$=\sqrt{\Sigma d^2/2n}$. "d" is the difference between corresponding measurements on two different films. "n" is the number of measurements.

The actual manner in which the S.E.m. was applied to the measurements in this study will now be described.

An F-test was performed using the highest and lowest S.E.m. for measurements between implants within each jaw. It was found that there was a significant difference between S.E.m. = .035 mm. for the middle maxillary to posterior maxillary measurement and S.E.m. = .173 mm. for the anterior maxillary to middle maxillary measurement. Significant differences were also observed between S.E.m. = .057 mm. for the middle mandibular to posterior mandibular distance and S.E.m. = .183 mm. for the anterior mandibular to posterior mandibular readings. All F-tests were done at $\alpha = .05$.

A re-examination showed that in the case of the high S.E.m's, one measurement was responsible. The F-test indicates that while significant differences may exist between specific sets of implants, it is more likely that the difference was due to error in reading the rule and punching the films. Also, the S.E.m. of .035 mm. is unusually small for cephalometric technics in which measurements more

precise than .1 mm. cannot be made.[3] Even the largest individual difference was only .4 mm., which in itself is small in relation to usual cephalometric errors. It is not likely that this difference is due to movement of the implant; for in all cases, if the difference was observed on the A-B combination, it would not be seen on the B-C and A-C sets for the same measurement, etc. For these reasons, the sub-sample difference was not considered meaningful, and one "grand" S.E.m. was calculated for all measurements between implants (no segregation made to specific measurements).

Also, individual S.E.m.'s for each specific measurement between cephalometric landmarks and implants, and between boney landmarks were calculated. No pooling was done here, because other well done studies using large samples have definitely shown that significant differences exist between measurements involving any cephalometric landmarks.[3]

As a matter of side interest, films A, B, and C for each subject were superimposed over the implants to visually observe how well this could be done.

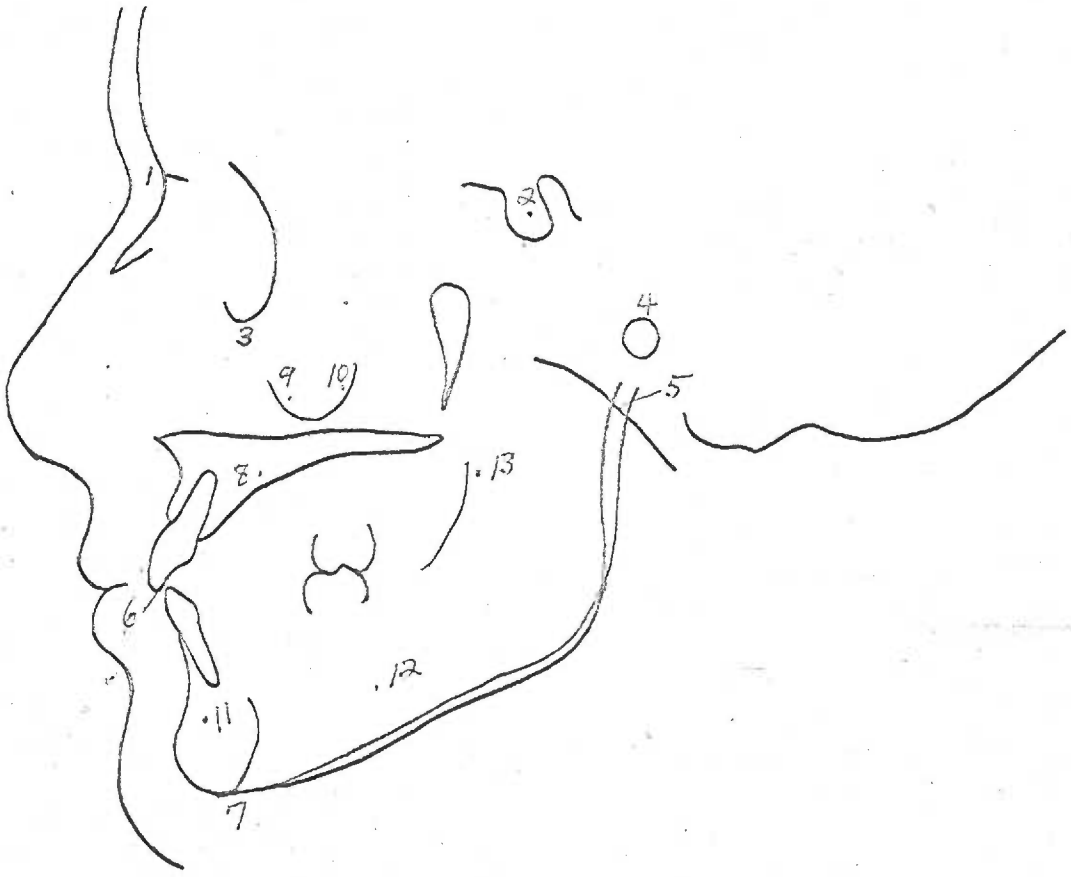

Figure 1. Reference points from which measurements were made.

1. Nasion
2. Sella
3. Orbitale
4. Porion
5. Articulare[3]
6. Incisal edge of upper right central incisor
7. Gnathion[3] - point where outer cortical structure of the inferior border of the symphysis meets the inferior border of the mandible

8-13. Implants

RESULTS

Measurement	n	S.E.m.
Between implants (marked)	195	.11
Implant--nasion (marked)	21	1.11
Implant--sella (marked)	21	.59
Implant--articulare (marked) (Mandibular)	21	1.14
Implant--gnathion (marked)	21	1.09
Implant--articulare (marked) (Maxillary)	21	1.88
Sella--nasion (tracing)	21	1.25
Sella--nasion (marked)	21	.83
Orbitale--porion (tracing)	21	3.39
Orbitale--porion (marked)	21	1.35
Upper central incisor--articulare (tracing)	21	1.51
Upper central incisor--articulare (marked)	21	1.19

Table 1. Standard errors of the measurement for measurements between implants, measurements between implants and selected cephalometric landmarks, and measurements between selected cephalometric landmarks.

DISCUSSION

From the compiled S.E.m.'s in Table 1. it is apparent that measurements between implants are quite reliable (S.E.m.=.11 mm.) and considerably more accurate than any other combination of measurements employed.

The measurements between cephalometric landmarks and implants were the next most reliable as a group. The S.E.m. for a measurement from an implant to sella indicates that this landmark was the most reliable of those used. Articulare was the least reliable of the boney landmarks measured in this group (see discussion regarding articulare in the radiographic technic section of the appendix).

The measurements between cephalometric landmarks indicate that the sella to nasion combination was the most reliable. It compared favorably with the implant to landmark measurements being only less reliable than the implant to sella combination of the group. As expected the orbitale to porion distance measured on a tracing was the least reliable of all but became much more accurate when measured directly on the film.

All of the measurements made on tracings were less reliable than those made directly on a marked film.

A comparison of the S.E.m.'s for the measurements between marked cephalometric landmarks in this study and those determined by Bjork[3] is interesting. The Danish

investigator found an S.E.m. of 0.30 mm. for the sella to nasion distance, 0.35 mm. for articulare to upper central incisal edge, and 2.19 mm. for the porion-orbitale measurement. This study produced S.E.m.'s of 0.83 mm., 1.19 mm., and 1.35 mm., respectively, for the same distances. One can say that they are fairly similar, the differences being due presumably to sample size.

Also, the measurements between maxillary and mandibular implants were just as reliable as those between markers confined to the jaws. Thus, indicating that all the subjects, the orthodontic patient included, could repeatedly occlude in the identical habitual centric position.

Superimposition of the three films for each patient confirmed the low range of computed S.E.m.'s for the implant measurements. No movement of the markers within the bone could be detected in any of the subjects for the duration of the study.

There are undoubtedly other ways of statistically analyzing the data. One method is to compute the variance of a single measurement on the three films for each subject; $S_i^2 = \frac{\Sigma X_i^2 - \frac{(\Sigma X_i)^2}{3}}{2}$ assume the variance is the same between subjects (or first test this by doing a Bartlett's test for homogeneity), and pool the variances.[19] This is almost the same as the method used, since the S.E.m. is a derivation of the pooled variance formula. Utilizing the S.E.m. has the advantage of not only being a valid procedure, but also it is a common statistic used by men working with measurement error and

reliability. Its use, therefore, allows such a comparison as was just made to be done.

SUMMARY AND CONCLUSIONS

Metallic implants were placed in seven subjects using a modified method patterned after the work done by Bjork.

The method used was found to be quite satisfactory in terms of placement success and post-operative sequelae.

The statistic, standard error of the measure, was used to evaluate the reliability of the implants as measurement reference points. This statistic was also applied to measurements between implants and selected cephalometric landmarks, and between a few boney landmarks. The measurements between implants were found to be the most reliable with a S.E.m.=.11 mm.

The chief criticism that can be made regarding the validity of the study is the small unrepresentative sample used. The figures given here must be interpreted with this in mind.

The duration of the study was too short to evaluate the long-term stability of the implants, which were apparently stable during the two weeks following placement.

Also, the fact that there were significant differences between implant measurements means that a future investigator should repeat reliability determinations on his sample.

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APPENDIX

Construction of Implanting Device and Preparation of Implants

The implanting device or "implanter" was constructed from tubing of various diameters and the spindle combination and thrust rod of a dental handpiece. The tubing, except for one size, is readily available through an orthodontic supply house (Unitek). The largest diameter tubing used (.082 ID x .1265 OD) may be purchased from the Alaskan Copper and Brass Company, Portland, Oregon. The handpiece parts were obtained from discarded S. S. White #4 Doriot handpieces or Parkell #4 Doriot handpieces. The individual parts may also be ordered from the respective companies for approximately $25 to $40, the Parkell parts being cheaper. The S. S. White mechanism was preferred because the larger threads on the two piece spindle had less tendency to strip or bind. Otherwise, the two are identical.

The implants were prepared from .022 inch diameter wire composed of 90% tantalum and 10% tungsten, which was graciously donated by the Wah Chang Corporation of Albany, Oregon, courtesy of Mr. Don Beggs and their research and development staff.

The wire was fashioned by first squaring one end with a "Joe Dandy" disc and then placing this end at right angles against the heavy band material soldered to the Crescent wire cutter shown on the following page (Figure 2). The cutter was held with the band material down against a flat surface, and the squared wire was inserted between the blades from above. The cutter was then raised from the flat surface

Figure 2. Wire cutter with heavy band material welded to one blade.

and the handles squeezed to cut the wire. This final step is important for if the wire is cut against the flat surface, the band material becomes dented and causes subsequent implants to be of varying lengths. The bevel of the blade of this particular cutter was such that implants of a constant 1-1½mm were produced. The welded band material on the cutter also served to catch the cut implant and prevented it from flying away. The pinched end of the implant was left bevelled, for this served as a point, allowing it to be driven more easily into bone without skidding.

No attempt was made to remove the small bur produced from squaring the other end of the implant before it was cut. This bur makes the diameter slightly larger than .022 inch in one plane and serves to keep the implant from falling out of the implanter when it is held vertically with the point down, as when placing the mandibular markers.

The procedure of forming the implants is not nearly as complicated as detailed description seems to make it, for several uniform markers may be produced in rapid succession.

The implanter was constructed as follows: Figure 3 on the following page is a flow sheet photo of the internal construction of the implanting device. A. is a piece of .022 inch diameter stainless steel wire. B. is .038 in. outside diameter by .023 in. inside diameter Inconel tubing (Unitek 500-320, TL-020). C. is .0635 OD x .0385 ID Inconel tubing (Unitek 500-636, HL-036). D. is .081 OD x .064 ID Inconel tubing (Unitek TL-062; not listed in 1965 catalog,

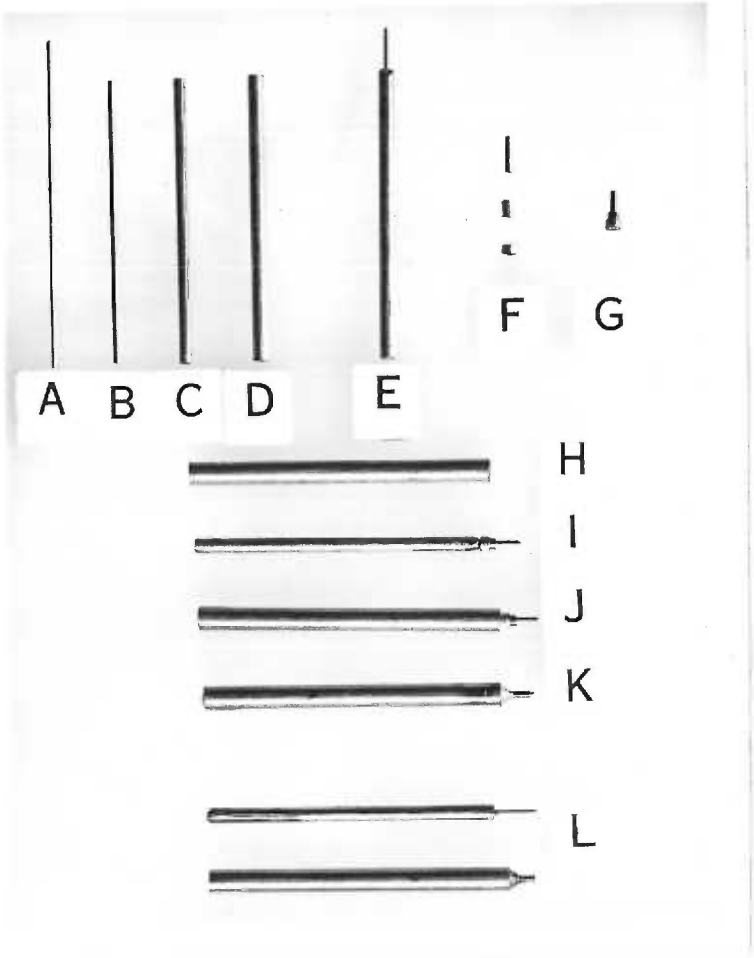

Figure 3. Flow sheet photo of internal construction of the implanter.

but was in 1964). B. was slipped inside of C., and this combination was then inserted into D. All three pieces of tubing were then cut simultaneously into lengths approximately 38 to 39 mm. long with a "Joe Dandy" disc (Figure 3 shows lengths already cut down from the 12 inch shipping length). A. is cut to a 44 mm. length and is inserted inside of the "triple" tube described above, with about 6 mm. protruding from one end as in E. There should be about ½ mm. of the wire protruding from the opposite end also. This latter end was then heated in a flame and soldered to unite all the tubes and the wire. Care should be taken to avoid flowing solder onto the sides of the tube. It should be confined just to the end.

There are several reasons why the above procedure was followed. This part, E., is the "driver" which contacts the implant and pushes it into the bone. The .022 wire after a period of useage has a tendency to become flattened and spreads at the tip so that it will not slide through the outside sleeve to be described later. Since this part was soldered on the end furthest from the implant, it can readily be reheated until the solder flows, and the .022 wire pulled out. A new wire could then be placed utilizing the same "triple" tube, without destroying the temper of either the wire or the tube. (No replacements were found to be necessary for the seven subjects in this study.)

Also, by soldering as described, the junction of the "triple" tube with the protruding wire is a sharp right angle. Placing solder at this junction would have produced a curved

angle, which would not provide as definite a stop for the driver against the outside sleeve.

F. in Figure 3 illustrates the component parts of the "tip" of the implanter. The assembled tip is shown in G. It is constructed as E. was, by placing 12 in. lengths of tubing the sizes of B., C., and D. inside each other but with the "B-size" tubing protruding 3 mm. beyond the "C-size" tubing, and with the "C-size" length extending 1 mm. beyond the "D-size" tubing. The three tubes were then spot welded together, with welds being made on the 1 mm. extension of C. and on D. (Rocky Mountain welder control set at $3\frac{1}{2}$-4). The telescoped tube was then cut all the way through to an overall length of approximately 5 mm.

Spot welding was utilized rather than soldering because part G. later fits inside of the outside sleeve, and soldering might enlarge the diameter so much that it could not be inserted. Also, this tip or point is the section of the implanter which contacts bone and holds the implant; therefore, its temper or hardness should be carefully maintained by avoiding several heating procedures (tip G. is later subjected to two soldering procedures of necessity).

H. in Figure 3. represents what has been referred to previously as the "outside sleeve." It is .1265 OD x .082 ID stainless steel tubing (Alaskan Copper and Brass, Portland, Oregon) cut to a length of 40 mm.

The final phases of construction of the internal parts of the implanter will now be described. Part G. was placed

on the wire protruding from part E. as shown in I. The I. combination was then inserted inside of H. to form the combination J., which was soldered as shown in K. The opposite end of H. from the tip was then shortened so that the driver tubing was flush or protruded slightly when seated fully in the outside sleeve. E. may then be removed from the outside sleeve-tip combination as in L.

Some details should be mentioned regarding the soldering of G., the tip, to H., the outside sleeve. The reason E. was used to hold G. was to accurately center or align the tip. Without E., there is enough freedom of movement between G. and H. that the tip might be soldered at an angle to the long axis of the outside sleeve, thus making it impossible to insert and drive the implant later. Also, G. should protrude beyond H. about 4 mm. such that the largest member of the telescoped tube is almost completely inside of H. This overlapping was done to facilitate the flow of solder, and to make a more rigid joint than a butt joint would be. Painting an anti-flux, such as alcohol and gold rouge, on the driver, E., was found to be a necessary procedure to keep solder from flowing onto it. Accidental soldering of the driver to the outside sleeve was also avoided by <u>not</u> sliding G. all the way onto the wire protruding from E., so that a gap was present between G. and the tubing of the driver.

Figure 4 on the following page is a flow sheet showing the construction and adaptation of the handpiece parts of the implanting device.

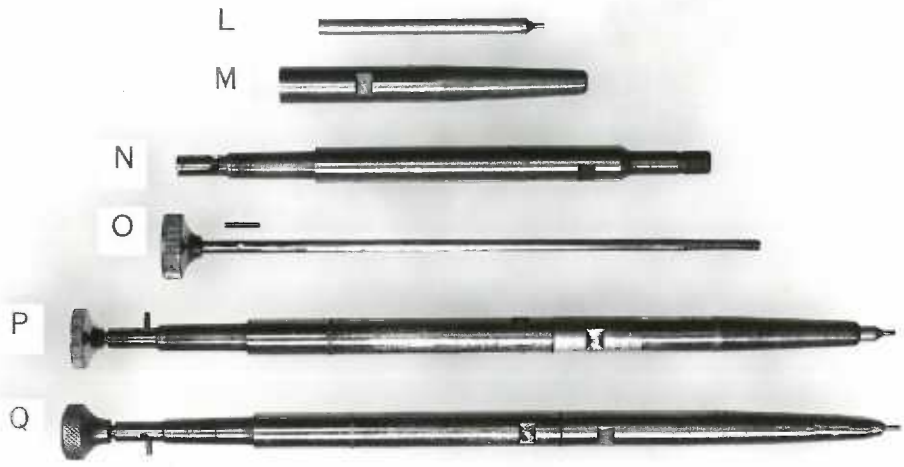

Figure 4. Flow sheet photo of adaptation of the handpiece parts of the implanter.

L. in this figure is the outside sleeve-tip combination shown as the bottom part in L. of Figure 2. M. is what will be referred to throughout the paper as the "lower handpiece part." N. will be referred to as the "upper handpiece part." O. will be called the "push rod."

M. has been adapted by using a red ticonium finishing stone to enlarge the diameter of the opening of the tapered end. This enlargement is to allow for insertion of L. later. Grinding with the red stone was best accomplished by shaping it to a smaller diameter than M. on a "Joe Dandy" disc before trying to insert it into M. If this was not done, the stone usually would bind inside of the part and shatter. By trial and error, the diameter was enlarged just until L. would slide inside the tapered end of M. In one instance where this enlargement was made too great, L. was wrapped with .125 in. thickness band material. This removed any existing play between the two parts.

N. was adapted similarly to M. by enlarging the threaded end with the same type red stone, except that the stone was shaped to a much smaller size before starting. This enlargement of the upper handpiece part was to allow the push rod, O., to slide completely through N. and essentially removed the threads on the inside of N. The outside threads were not distrubed. In addition, N. was further modified on the opposite end by cutting an L-shaped slot into the smallest of the telescoping sections (shown in photo, but rather obscure). This slot was cut with a #557 FG bur in a high speed air driven handpiece and was started in the groove

which already existed in this handpiece part. The vertical leg of the L-shaped slot was extended to about 2 mm. from the next larger section of the telescoped part. At this point a right-angle cut was made to form the horizontal leg of the L-shaped slot. This part of the slot was extended 2 to 3 mm. At the end of this, a short vertical leg was cut back toward the end where the entire slot was started. This short section of the slot is at right angles to the horizontal component and parallel to the other vertical element. It is extended for only 1 mm. at this time (see Figure 5 below).

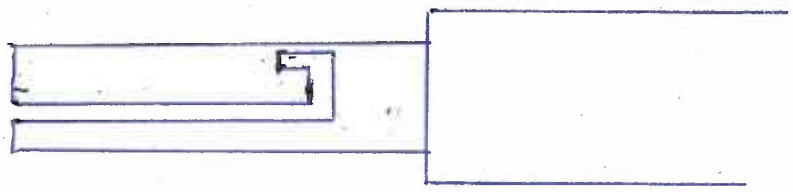

Figure 5. Slot diagram.

The slot just described will later accommodate a spur the size of an .045 in. stainless steel wire, so the cut should be made as straight and steady as possible. Hand holding is adequate. If some areas of the slot need to be enlarged to allow free sliding of such a wire, it may be done alternately with a sandpaper disc and a #557 tapered

fissure bur for the belt driven straight handpiece. This last procedure also smooths the slot.

Part O., the push rod, was modified by first squaring the threaded end with a disc but not shortening it into the threaded portion. A large carborundum wheel was then used to blunt the threads. This served to narrow the diameter slightly and to allow the rod to slide freely inside of the upper handpiece part, N. The procedure can conveniently be done when the diameter of N. is being enlarged.

O. was then placed inside of N. so that the knurled nob of O. was touching the end of the section of N. with the prepared slot. A #1 round bur in a slow speed straight handpiece was used to place a mark on O. where it could be seen through the horizontal section of the slot cut in N. The push rod was then removed from N. and a hole was cut through the rod so that it was centered through the greatest bulk of metal. The mark just referred to was used as a starting hole. A #2 FG round bur was used in a high speed air driven handpiece. Handholding is adequate.

A piece of .045 stainless steel orthodontic wire about 6 mm. in length (see Figure 3) was then forced into the somewhat undersized hole. A vice and a hammer was used. The friction grip created was enough to retain the wire spur through all implantation procedures. A disc was used to smooth the opposite side of the rod from which the wire protrudes.

Final assembly of the implanting device consisted of

screwing M. onto N. and inserting O. into both as far as the knurled nob and spur would allow (spur should be locked into the horizontal part of the slot on N.). L. was then dropped into the open end of the combination until it was stopped by the push rod, as in P. The driver, E. of Figure 2., was not inserted into the outside sleeve-tip, L. The lower handpiece part was then well heated in a flame near its junction with the protruding outside sleeve-tip combination and silver solder applied. The solder used in all instances throughout construction was Unitek Formula #6 silver solder. If the flame is directed primarily onto the lower handpiece part, no melting of the solder previously placed on the outside sleeve-tip combination occurs. The joint was passivated and polished with flour of pumice. The completed implanter is shown in Figure 4, Q.

A few additional adjustments may be necessary before the apparatus can be used. First, unscrew the lower handpiece part and drop in the driver, E., with the protruding wire toward the tip. Tap the side of the lower handpiece part lightly until the driver falls into place in the tip. Re-screw the lower handpiece part back onto the rest of the device (push rod is still locked in the horizontal section of the slot). If the lower part cannot be screwed on all the way without force, remove the push rod, O., and shorten it bit by bit, until the lower part can be replaced completely and easily.

Second, observe how far the protruding wire of the driver extends beyond the tip. Shorten until it extends

only about $\frac{1}{2}$ to $\frac{1}{2}$ mm. (This is to countersink the implant into the cortical plate.)

Third, unlock the push rod by twisting until the spur engages the short vertical section of the slot cut in the upper handpiece part. With a piece of .022 orthodontic wire push the protruding end of the driver up inside the tip. Then insert an implant using a mosquito hemostat. The bi-bevelled point of the implant should extend just beyond the end of the tip or be nearly flush with it. If it protrudes further, remove the push rod and lengthen the short section of the L-shaped slot a bit at a time using a #557 tapered fissure bur in a slow speed straight handpiece. Periodic checks should be made by reinserting the push rod and implant until the bevel only slightly protrudes. This step is important, for if the implant extends too far beyond the tip, it is not accurately directed into the bone when placed. If it is short of the tip, the tube could conceivably become clogged with tissue which would have to be expelled before the implant could enter the bone. The soft tissue might then become buried beneath the cortical plate. If shreds of periosteum are buried with the implant, the marker may become encapsulated in connective tissue. This could allow movement of the implant, making it an unreliable point for measurement.[4]

This completes the description of the construction of the implanting device.

Sterilization Procedures

Since the handpiece parts of the implanter are not stainless steel and therefore subject to rust, a method other than steam autoclaving was desired. (The anti-rust sprays were not available.) The Harvey alcohol vapor sterilizer was the most satisfactory for this purpose and was quite convenient to use.

Four bacterial culture tests on the processed implants were done to check the effectiveness of this type of sterilization. These all failed to grow any organisms.

From the regimen used by Bjork, a sterile implanting device was used for placement of each implant,[4] rather than using one implanter for all the placement sites. Bjork felt he had less incidence of periostitis because of this precaution. The implanting procedure also was facilitated by having the implant already loaded in the device, for it was found to be somewhat tedious to place an .022 in. diameter pin in an .023 in. diameter tube without contaminating the tip and the implant.

The following detailed procedure was followed: After the implants were placed, the push rod was removed, the upper and lower handpiece parts were unscrewed, and the driver was pushed out of the lower handpiece part with a length of .022 wire. The parts were all scrubbed with water and a germicidal soap. The driver and tip of the lower handpiece part were carefully inspected for damage. When used on a few of the adult subjects with very hard bone, the driver

was flattened enough that it could not be removed from the tip. In these instances, a fine diamond separating disc was used to reshape the point of the driver until it could be removed from the lower handpiece part. The point of the driver was then squared off, and the tip of the lower handpiece part was shortened and dressed slightly. The driver was then reinserted to see if it still protruded about ¼ to ½ mm. beyond the tip, and suitable adjustments were made if it did not.

Next, the inside and outside of all parts were wiped with 90% ethyl alcohol using a pipe cleaner and a gauze sponge. An .022 wire was dipped into the alcohol and inserted in and out of the tip a few times.

The same process was repeated, using ethyl ether. The ether was used to insure removal of some of the lipoid products of blood which are insoluble in water and alcohol.

The implanters were then assembled and reloaded. Johnson and Johnson Signaloc tape was wrapped around the device just under the spur of the retracted push rod. This was to prevent the push rod from sliding in the implanter and pushing the implant out if inadvertently held in a vertical position with the tip down while placing in the sterilizer.

The implanters were then wrapped in paper towels--six in one towel and two "spare" devices in another--and placed with the following items in the sterilizer: Bard-Parker handle with #15 blade attached, needle holder, needle and suture

material, dappan dish with extra implants, curved hemostat, surgical mallet, and a length of .022 wire. This "pack" allows for the unusual circumstance when sutures may be needed for hemorrhage control, and for the accidental unloading of several implanters before being used.

The sterilizer was operated in the usual manner, except that a 45 to 60 minute period was used instead of the recommended 15 to 20 minutes to insure full heat penetration to the inside of the implanters. After the time period was over, the tray was removed and air cooled. When the instruments were allowed to cool inside the sterilizer with the door cracked, moisture condensed on the implanters, and they rusted.

Technic of Implantation

The sites where implants were placed are indicated in Figures 6. and 7. (following page) by the circled areas. The usual procedure was to place three implants in each jaw. An intra-oral approach was observed in all cases. An outline of the general technic used will first be presented, and this will be followed by the detailed modifications made necessary because of the peculiarities of the individual locations.

Each of the six areas under consideration was first palpated to try to determine the position of near-by roots of teeth, the depth of the soft tissue, and the topography of the bone at the site. If the soft tissue layer is thin, the implant may be placed without an incision. This procedure was followed in only one instance--the posterior maxillary implant on subject P. L.--apparently with success and with similar post-operative findings as for those implants placed with the aid of an incision. In retrospect, the author is of the opinion that the two zygomatic process implants (posterior and middle maxillary) and the middle mandibular implant could be placed without incisions. It is doubtful that the other three sites could be done successfully in this fashion because of the thickness of the overlying tissue. Early trial placements on miniature swine indicated that those implants placed without the benefit of an incision to allow the tip to be placed directly against the bone wound up in the soft tissue when this tissue layer was thick (2 to 4 mm.).

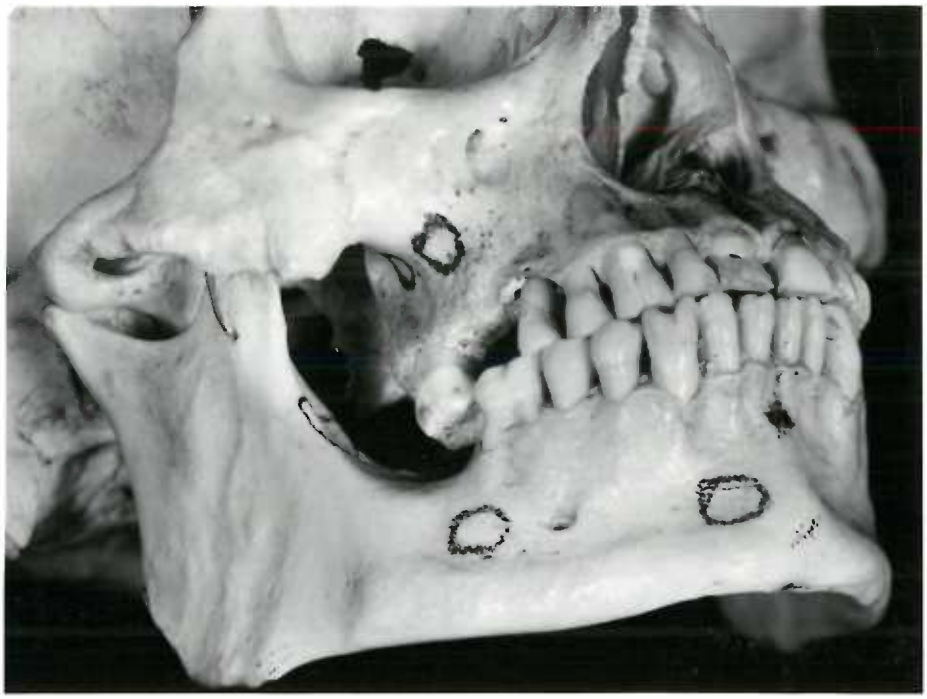

Figure 6. Implant locations.

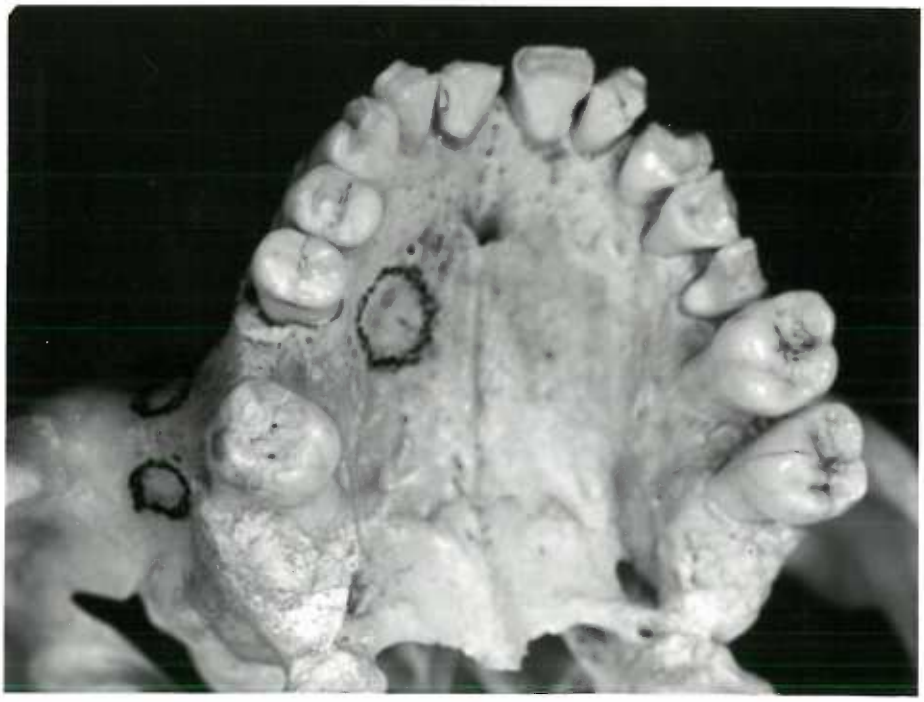

Figure 7. Implant locations.

This occurred on the palate (anterior maxillary implant) and where muscle layers had to be penetrated, such as the mentalis and buccinator in the anterior and posterior mandibular sites, respectively.

The topography of the bone is important, because the implant should enter at right angles to the surface. An angulation other than perpendicular might allow skidding of the tip when malleting, with the possible results that the implant may never enter the bone. According to Bjork,[4] entering at right angles allows complete penetration of the periosteum and countersinks the marker away from the pull of muscles inserted into the periosteum.[5]

After palpation, topical anesthetic was applied to all six areas. A few drops of local anesthetic was deposited at each site. One carpule was usually satisfactory for all the areas. The Bard-Parker handle with #15 blade attached was then used to make a stab incision directly over the implanting site down to the bone. This incision was made no longer than the width of the blade and no elevation of a flap of any kind was done. The incisions in the vestibulae were placed in a vertical plane to facilitate primary closure. One of the implanting devices was then taken from the tray. The six implanters were previously unwrapped, and the tape was removed from beneath the spur. One should be careful not to press on the push rod and accidentally unload the devices (see "sterilization procedures"). If hemorrhage occurred the site was blotted with sterile gauze sponges, and then the tip of the implanter was placed directly into

the incision. Considerable force was used to seat the tip firmly against the surface of the bone. With practice, this manual placement of the tip helps one to further ascertain the topography of the surface, and adjustments should then be made in the angulation to approximate a right angle with the surface. The middle of the implanter is grasped by the fingers of the right hand, and the left hand is used for retraction of the lip or cheek. Again, touching or pushing the push rod should be avoided; for if the tip is not against the bone when the rod is bumped, the implant will be deposited in the soft tissue.

Once the tip has been firmly pushed against the bone, the operator then uses his left hand to support the patient's head or mandible depending on which implant is being placed. During this change of position of the left hand, the angulation of the device should not be changed. The assistant then uses the surgical mallet to lightly wrap the nob on the end of the push rod. More than one blow should be used, and the first should be more of a test blow to determine how hard subsequent wraps should be. There was so much variation in the hardness of the bone that no instructions can be given regarding the strength of the blow. A great variation was observed not only between subjects of different ages, but between subjects of the same age; and even between sites within the mandible or maxilla, as well as the expected differences between the jaws. In general, however, the placement of maxillary implants requires softer blows than the placement of mandibular markers; and young subjects

need a much softer blow than adults (the weight of the mallet itself may be sufficient in children).

As many as 3 to 5 blows may be necessary. The number is determined by observing the position of the spur stop on the side of the push rod. When it has been driven the length of the short vertical slot section and is at the level of the horizontal section of the L-shaped slot referred to in the construction of the implanter, the implant has been completely driven and countersunk into the bone (providing the tip was not moved or skidded during the malleting).

Emphasis has been placed on the use of repeated "soft" blows because it was found not only to be more comfortable to the patient, but avoided driving the tip and the implant completely through the cortical plate. This of course, grossly fractures the plate, thus increasing post-operative pain and swelling; and may cause the implant to be lost in the soft tissue overlying the site, making it useless as a stable landmark.

Because of the great variability in bone denseness, the use of a spring loaded device to deliver a constant blow is unnecessary and would even detract from proper placement of the markers.

After ascertaining that the implant has been completely driven into the bone, the implanter is removed and placed out of sight of the subject. If hemorrhage persists, the site is momentarily blotted before proceeding to the next area where the same procedure was followed. Hemorrhage

was no real problem in any of the seven subjects, and no sutures were placed.

No specific post-operative instructions were given in most of the cases other than recommending aspirin for pain. Subjects P. L. and C. T. were told not to eat hot foods or liquids the first 24 hours, and to follow this with hot saline rinses. The healing of the implant sites did not appear to be any different from those in subjects given no instructions.

The most common post-operative symptom observed was a localized indurated edematous swelling at the site of each placement. This swelling gradually subsided over the period of the study. The palatal implant usually was not accompanied by any swelling, but mild hematoma was a universal finding. The anterior mandibular implant site usually not only displayed the swelling mentioned above, but also a hematoma of a mild nature. One subject developed a similar picture at the middle mandibular site, and another at the posterior mandibular site. There was apparently a direct relationship between the thickness of the overlying tissue and the amount of hematoma seen. The thicker the tissue, the greater the bleeding; and when the overlying tissue contained muscle, the hematoma was usually larger. It should be emphasized that none of the swelling seen post-operatively was great enough to be noticed externally to the mouth and often had to be palpated to be detected, even on the first or second day after the placement. Primary closure of the short incision generally occurred.

Most of the subjects reported having a mild dull pain for one or two hours immediately after the effects of the anesthetic remitted. Aspirin controlled this sensation. The symptom was described as more of an annoyance than a pain. After this period, the only pain experienced was when the sites were either palpated or the cheek or lip strongly retracted.

Some of the peculiarities of the individual placement sites will now be discussed.

The anterior maxillary or palatal implant ideally should be placed as far anteriorly as possible to get maximum distance between implants in the maxilla. This would not be necessary for this study, but later tooth movement studies involving superimposition of films would find long distances advantageous and more accurate. At the same time, the roots of the teeth must be avoided and allowances made for tooth retraction in orthodontic patients. The best guide seemed to be to place the implant between the two most posterior rugae on the right side at the junction of the alveolar process and the horizontal vault of the palate. This usually placed the implant just onto the lingual slope of the palate, posterior to the incisors. If the palate is very high and arching, the implant may have to be placed a bit more posteriorly to avoid the roots of the incisors; if the lingual slope is long and flat, the implant can be placed farther anteriorly. In mixed dentition subjects, the implant should be placed almost onto the

horizontal vault of the palate to avoid contacting developing permanent teeth.

The middle maxillary implant should be placed as close to the sharp crest of the zygomatic process as is possible to locate by palpation. For this reason, the anesthetic should be deposited high up in the reflex of the vestibule so that the fluid does not obscure the sharp crest of the process. The reason for this exactness in placement is to avoid breaking into the maxillary sinus of some adults, located just under the thin plate of bone 3 to 4 mm. superiorly to the crest of the process. A light blow should be used to start the implant.

The posterior maxillary implant was placed on the inferior surface of the zygomatic process as far posteriorly as possible. In some individuals, the process curves back on itself quite rapidly so that instead of an inferior surface, there is a posterior surface. When this condition exists, the implant cannot be placed properly since access will not allow the instrument to be held at right angles to the surface of the bone. If placement is attempted, the tip is quite likely to skid and cause the implant to be deposited in the soft tissue. For this reason, subject C. T. has just two implants in the maxilla. Actually, only two implants are needed for measurement purposes, but three make superimposition easier. When the anesthetic is deposited for this site, the needle can be used to aid in evaluating the shape of the process. If it curves up sharply as described above, the anesthesia is not utilized or the implant placed. If placed,

a light blow should be used.

The anterior mandibular implant was located just mesially to the cuspid in the adult patients and just mesial to the lateral incisor in the subject with a mixed dentition. The incision was actually made on the lip side of the deepest part of the vestibule and pushed through the mentalis muscle until bone was contacted. Depending upon the attachment of the lip, the implant can usually be placed anterior to and below point B (on the right side). Placement as far down on the chin point as possible is desirable to avoid any subsequent resorption at point B in a growing subject.[4]

The middle mandibular implant was placed in the bottom of the vestibule posteriorly to the mental foramen. In most subjects it was inserted beneath the first permanent molar. In subjects with mixed dentitions, placement below the first molar is important in order to avoid the developing bicuspid buds. It was found desirable not to place the implant so near the border of the mandible that it was necessary to pass through the buccinator muscle attachment. When this was done on two subjects, quite a bit more hemorrhage than usual was experienced, although it was controlled without the need of sutures. The buccal plate over the first molar and bicuspid roots appeared to be thick enough in all the subjects to accommodate the implant without contact with the roots. None of the subjects have complained of dental pain to date.

The posterior mandibular implant was placed between the anterior border of the ramus and the internal oblique line

(Sicher's temporal crest) above the retromolar triangle. This site was chosen because it is superior to the position occupied by an unerupted third molar, and because no thick muscle layers overlay the area. The massive bulk of the masseter and a few fibers of the temporal muscles lie immediately lateral to this site, and on many individuals the pterygomandibular raphe lies to the medial. According to Bjork's description of his procedure, an implant was placed on the lateral surface of the ramus to avoid the path of possible future resorption of the anterior border.[4] This investigator found that not only was the overlying tissue very thick, but that access to the lateral surface was such that the implanter could not possibly be held at right angles to the bone using an intra-oral approach. In young subjects, this implant may be uncovered by resorption, and it might be advisable to place all the markers in the body of the mandible. In this study, six of the seven subjects were adults, so the position of this particular implant should be fairly stable.

To conclude this section, a few general comments will be made, and some of the problems which arose should be described.

A specific order of placement of the implants was not followed, and there appeared to be no particular advantage in doing so.

None of the subjects appeared to be apprehensive or uncomfortable during the malleting. Most displayed far more anxiety during the injection of the local anesthetic.

Although the construction of the implanting device was somewhat complex, the actual placement of the implants requires no particular or special skill on the part of the operator (who should be a trained dentist) or the assistant.

The total cost of the eight implanters and the implanting material used in the study was approximately $10 to $12, not including the time of the investigator for the construction.

Finally, mention should be made of difficulties which arose with three of the subjects.

Subject, E. H. was the first to have the procedure done. Initially, only one zygomatic and one mandibular (middle location) implant were placed. At that time, the "one-blow" malleting technic, as described by Bjork,[1] was being used. The maxillary implant was apparently only partially driven into the bone because the flat end of it could later be palpated through the completely healed soft tissue. The first trial at placing the mandibular implant failed to even get the pin started into the bone, for it could be seen and palpated in the tissue. This was discovered at the time of placement, and a small periosteal elevator (#7 wax spatula) was used to elevate the sides of the incision. The implant was retrieved with a curved hemostat. Another implant was placed immediately at the same site, also using the one-blow technic. By palpation and visual observation, this implant was apparently properly seated in the bone. The subject experienced no particular pain at either site, but developed what probably was a mild periostitis at the

mandibular location. Two additional implants were placed 13 days later (one in maxilla and one in mandible) using the "multiple light blow" technic, and these healed uneventfully. Apparently, the more severe post-operative reaction experienced with the first mandibular implant was due to the increased trauma of recovering the one marker from the soft tissue. The first-placed implants (one blow technic) were included in the measurement study, and even though there exists some doubt as to their complete seating in the bone, measurements involving them have no more error than those measurements involving the implants placed later (see data sheets).

Subject B. T. had eight implants placed instead of six, because two of the first six were not driven completely into the bone. No attempt was made to remove them, but one additional marker was placed in the vicinity of each of the incompletely seated pins. The two poorly driven implants were malleted with one blow, but all others were driven with several lighter taps. All implant sites healed uneventfully. All implants were included in the measurement study, and all appear to be equally stable to date (as judged by the standard errors of the measure involving them).

Subject C. T. had the two zygomatic process implants work free, and she recovered them from the oral cavity. The multiple blow technic was used in this case, but it was felt that the blows used were too hard and the tip was placed too far superiorly on the process. In fact, at the time of placement the operator observed that the tip of the instrument felt as if it had been buried in the cortical plate or

had passed completely through it. Some fear was expressed that the implant might have been driven into the maxillary sinus. This was not the case, apparently, since the implants were lost about one hour after placement. However, the cortical plate must have been fractured and unable to hold the implants. The subject also experienced a similar post-operative reaction as subject E. H. at these sites, again indicating that trauma was probably the cause of the reaction. A single zygomatic implant was later placed at a more inferior position directly over the crest of the process (see earlier mention of this). This implant was not lost, and the site healed uneventfully.

One added point should be made. Emphasis has been placed upon placing the implant in the cortical plate and not passing through it. The purpose of this is to avoid using a heavy blow and grossly fracturing the plate. This fracturing may allow the implant to fall out of the bone and be lost in the overlying tissue or fall into the oral cavity as in subject C. T. The statement was not meant to mean that the implant might be lost in the marrow spaces by passing through the cortical plate. This cannot physically occur since the marrow spaces are only about 50 to 200 microns at their largest dimension while the implant is 500 microns in diameter and 1500 microns long.

Radiographic Technic

The cephalometer used in this study was a Universal self-centering head holder with the orbital indicator and nasal holding devices removed. A constant midsagittal plane-film distance was used throughout the study. The tube target-film distance was maintained at 84 inches. Therefore, the magnification was the same for every film.[8,9,18]

A Machlett Dynamax "50" X-ray tube with ½ inch focal spot and rotating anode was used as the source of radiation. The tube was properly filtered and collimated and was supplied with a moveable aluminum wedge to vary soft tissue penetration. A Profex control console completed the radiographic apparatus. The headholder and tube were not fixed together (each independently moveable), and since the subjects were radiographed in a standing position, an optical sighting system was utilized to align the tube with the level of the earposts.

A 100 line per inch Lysholm grid was used to minimize the scatter radiation. Blue Brand Kodak medical X-ray film, size 10 x 12 was coupled with a bakelite front cassette containing high speed screens.

Due to the inability to vary the kilovoltage of the apparatus in small stepwise increments, a constant 120 KV and 25 MA were used throughout the study. The time was varied from 2/5 second to 1 second depending on the age and size of the subject. Either 7/10 second or 1 second was used on all the adult subjects, and both 2/5 second and ½ second were used on the child subject (the ½ second

producing the better film on this rather large seven year old).

An interesting finding was made during the study regarding exposure values. It was found that the time of the exposure (either 7/10 second or 1 second) for the adult subjects could rather accurately be estimated by the hardness of the bone at the implant sites as judged by the amount of force needed to drive the implants to place. Those subjects which required more force and/or more blows were exposed for 1 second, and those which needed a lighter blow were exposed for 7/10 second. The quality of the films produced in this manner was very desirable.

The density of the films used was similar to any good quality high kilovoltage film used for diagnosis in orthodontic treatment. The film was of long scale contrast, but all the usual landmarks could be seen. In other words, the headplate was made up of many shades of gray, rather than sharply contrasting blacks and whites. The tantalum-tungsten implants showed up equally well at all exposures; however, they began to burn out when the film was markedly overexposed. None of these heavily radiated plates were used in the study. A photograph showing the ease with which the implants could be visualized follows on the next page. (Figure 8., photo does not accurately reproduce the soft tissue profile present on the film.)

All films were developed for five minutes, fixed for twenty minutes, rinsed for thirty minutes, and then dried. The usual dark room procedures and precautions were followed.

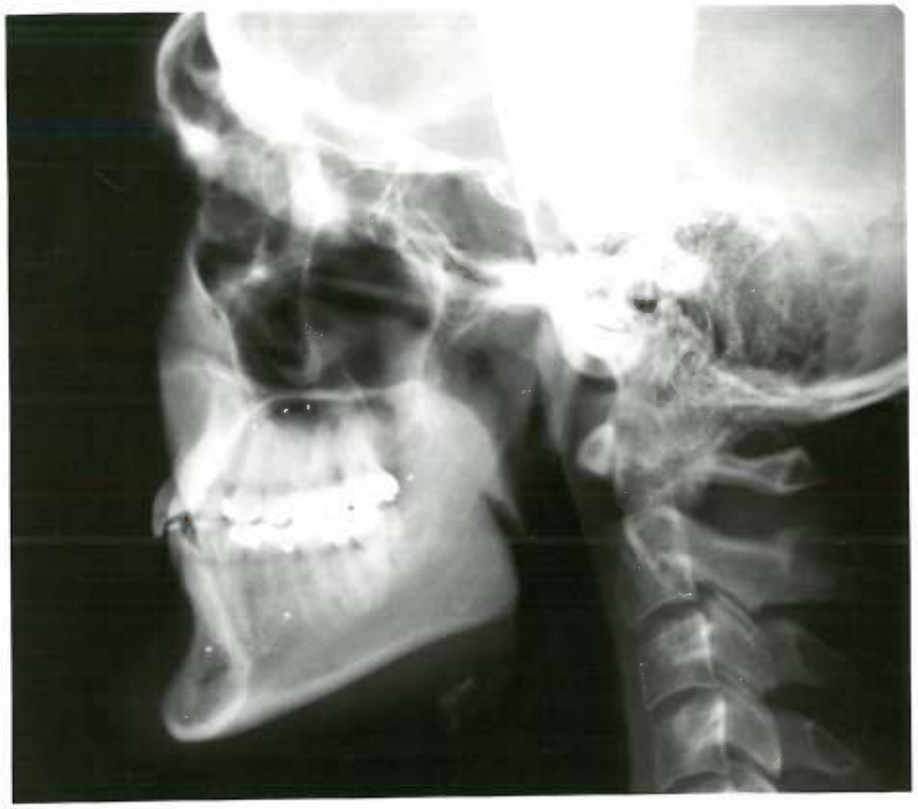

Figure 8. Position of implants on lateral headplate.

To repeatedly position the subjects the same in the head holder, the following procedure was followed: First, the height of the holder was adjusted approximately to that of the subject. The patient's head was eased between the ear posts, and they were gently moved into the patients ears until snug. The side of the face containing the implants (right) was placed next to the grid. The head holder was then raised slightly to, in a sense, "raise the patient by the ears." The subject was then asked to try to turn his head back-and-forth. If this could be done through more than 1 to 2 degrees, the ear posts were narrowed slightly, just short of producing pain. The subject was then asked to look straight ahead. This allowed the patient to position his head to the horizon. Since rotation around the ear posts as an axis would produce no error in this study, no nasal positioner was used. The patient was then told to "bite on your back teeth and hold very still," and the film was exposed.

To close this section, the author would like to make two suggestions that might contribute to even greater accuracy of measurement in future studies.

If articulare or gonion are to be used as points from which measurements are to be made, it is suggested that the subject have his head tipped up slightly to get the posterior border of the mandible off the cervical vertebrae and posterior wall of the pharynx. This should make the posterior border easier to follow for location of articulare or construction

of gonion.

Also, if a number of subjects are readily available for a particular study (they were not for this study), it would be advantageous to select those patients whose headplates are of highest quality. Some individuals just have sharper headplates than others no matter what adjustments are made. One might coin the term "radiographability" to describe this point.

Derivation of S.E.m. Formula[19]

Formula for standard error of the measure:

$$S.E.m. = \sqrt{\frac{\Sigma d^2}{2n}}$$

Same formula written as a variance rather than a standard deviation:

$$S.E.m.^2 = \frac{\Sigma d^2}{2n}$$

n = number of subjects measured (sample size)

d = difference between two measurements, X_1 and X_2 in each subject

$$d = X_1 - X_2$$

$$\Sigma d = \Sigma (X_1 - X_2)$$

The formula then becomes:

$$\text{I.} \qquad S.E.m.^2 = \frac{\Sigma (X_1 - X_2)^2}{2n}$$

Formula for pooling variances from different samples having equal variances but different means:

$$\text{II.} \qquad s_p^2 = \frac{\Sigma (X_1 - \bar{X}_1)^2 + \Sigma (X_2 - \bar{X}_2)^2 \ldots\ldots + \Sigma (X_K - \bar{X}_K)^2}{n_1 + n_2 \ldots\ldots + n_K - K}$$

$n_1 \ldots$ etc. = number of items or individuals in each sample

X = a measurement or observation (subscript here labels the individual sample)

$\bar{X}$ = mean of the values in each sample (mean of the measurements)

K = a constant equal to the number of categories

Let us now see how the S.E.m.^{2} is a special case of pooling the variance where there are "n" samples with two observations or measurements in each sample. To do this, an example will be used-- the sample used in this study. Therefore, in formula II. there will be seven samples ($n_1, n_2, \ldots n_7$) each containing two measurements. k is a constant subtracted from the denominator

and is equal to the number of categories or samples, in this case seven. The formula then becomes:

III. $$S_p^2 = \frac{\Sigma(X_1-\bar{X}_1)^2+\Sigma(X_2-\bar{X}_2)^2 \ldots\ldots \Sigma(X_7-\bar{X}_7)^2}{2(1+1+1+1+1+1+1)-7}$$

Let us work with just the numerator of the above formula and consider only one sample or individual, so no subscripts will be needed to label the sample:

$$\Sigma(X-\bar{X})^2$$

Since $\bar{X}$ is the mean of the measured values, by definition--

$$\bar{X} = \frac{\Sigma X}{n}$$

ΣX = sum of the measured values
n = 2 (number of values)

$$\therefore \quad \bar{X} = \frac{\Sigma X}{2}$$

The formula can then be revised as follows:

$$\begin{aligned}\Sigma(X-\bar{X})^2 &= \Sigma\left(X^2-2X\bar{X}+\bar{X}^2\right)\\ &= \Sigma X^2-2\Sigma X\frac{\Sigma X}{2}+2\left(\frac{\Sigma X}{2}\right)^2\\ &= \Sigma X^2-(2\Sigma X^2/2+2\Sigma X^2/2^2\\ &= \Sigma X^2-(2\Sigma X^2/2+\Sigma X^2/2\\ &= \Sigma X^2-\Sigma X^2/2\end{aligned}$$

* See reference #19 in bibliography (p. 19)

ΣX in the formula represents the sum of the measured values, and in this study two measured values were made per individual, therefore: $\Sigma X = X_1 + X_2$ and the formula then becomes:

$$X_1^2+X_2^2-\frac{(X_1+X_2)^2}{2} \quad \text{or} \quad X_1^2+X_2^2-\frac{X_1^2+2X_1X_2+X_2^2}{2}$$

which may be revised as follows:

$$\begin{aligned}X_1^2+X_2^2-(X_1^2+2X_1X_2+X_2^2)/2 &= X_1^2+X_2^2-\tfrac{1}{2}X_1^2-X_1X_2-\tfrac{1}{2}X_2^2\\ &= \tfrac{1}{2}X_1^2+\tfrac{1}{2}X_2^2-X_1X_2\\ &= \tfrac{1}{2}(X_1^2-2X_1X_2+X_2^2)\\ &= (X_1^2-2X_1X_2+X_2^2)/2\\ &= (X_1-X_2)^2/2\end{aligned}$$